

**REMARKS**

Claims 3, 4, 6, 8, 9, 13, 14, 16, 18, 19, 21, 22, and 24-38 were pending in the present application. Claims 3, 4, 6, 8, 9, 13, 14, 16, 18, 19, 21, 22, and 38 are withdrawn from consideration. By virtue of this response, claims 24-37 are under consideration.

Claims 24 and 31 are amended to correct a typographical error. Applicant amends the claims to insert "a" before the first occurrence of the word "catheter". Support for these amendments can be found in the application as filed, for example see the Abstract as well as paragraph [0052].

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicant believes the amendments do not present any new matter to the subject application.

**Rejections under 35 U.S.C. §103()**

Claims 24-29 and 31-36 are rejected under 35 U.S.C. §103(a) as being anticipated by Huebsch et al. (5,853,422) in view of Shaw et al. (6,080,182). Applicant disagrees that the Office Action establishes a proper *prima facie* case of obviousness.

Applicant repeats the previously submitted argument and again respectfully refer to MPEP §2141.02, which explicitly states that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (as also cited in MPEP §2141.02).

Huebsch clearly fails to teach a self-expandable septal defect occluder. See lines 16-20 of Col. 2 in Huebsch, which explicitly recite the need for a plug that is adjusted by mechanical means from a delivery configuration to a configuration which functions as a plug at the site of a defect. In addition, in cols. 5 and 6, Huebsch teaches a complex mechanism to lock the ends of the Huebsch device together. The Huebsch device also teaches mechanisms to lock the expanded device together. see Figs. 6-10.

Applicant again repeats previous arguments that Huebsch clearly teaches a complex device that requires actuation for deployment. Applicant's specification actually refers to devices such as the Huebsch device when reciting that "[m]ost trans-catheter systems are

mechanically complex and require a great deal of remote manipulation for deployment or retrieval. This extensive remote manipulation, such as by applying tension to one or more cables in order to deploy or to anchor the device in place, not only increases the difficulty of the procedure, but tends to increase the likelihood that the device will be improperly deployed. This can necessitate either retrieval or repositioning so as to effectively occlude the defect and minimize the risk of embolization.” (See paragraph [0006] of the subject application).

Clearly, applicants’ claims recite a self-expanding device to overcome the deficiencies of devices similar to the Huebsch device. Moreover, when considered in its entirety, the Huebsch reference simply fails to teach or suggest the requirements of applicant’s claims.

With regard to the addition of Shaw et al.; Applicant again respectfully notes that the teachings of the references being combined in an obviousness rejection are not sufficient to render the claims prima facie obvious if any proposed modification or combination of the references change the principle of operation of the reference invention being modified (See MPEP. §2143.01 VI).

Again Huesbch explicitly states that the invention disclosed therein satisfies a need for a plug that is adjusted by mechanical means from a delivery configuration to a configuration which functions as a plug at the site of a defect. Re-engineering a device that is adjusted by mechanical means to one that is self-expanding certainly appears to change the principle operation of the device. For this reason alone, applicant believes the combination is improper.

Yet, even apart from the above, Shaw teaches a device having a fluoropolymer membrane supported by an embedded wire structure (see Abstract of Shaw). The wire structure of Shaw radially and circumferentially supports a membrane, providing greater central support to the membrane. (col. 2, lines 36-46). Shaw specifically teaches that these devices rely on the support structures having curved outer surfaces to minimize tissue erosion. (Shaw col. 2, lines 36-46).

In *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395-97 (2007) the U.S. Supreme Court instructs that the key to supporting any rejection under 35 U.S.C. 103 is a clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court also noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The only guidance provided by the Office Action, is that it would have been obvious to make the Huebsch device self-expanding in order to facilitate the insertion of the device. However, applicant is unable to fully respond since there is no discussion by the Office Action as to why one would completely disregard the express teaching of Huebsch and modify the device. Furthermore, the applicant is also unable to address any analysis by the Office Action as to why one would then continue to disregard the majority of teachings of Shaw and construct a device as suggested in the previous Office Action. If one were to follow the teachings of Shaw, the structure of Huebsch would be replaced by a wire supported membrane structure.

In view of the above, applicant submits that believes that the Office Action fails to establish a proper prima facie case of obviousness. Accordingly, applicant requests allowance of the subject claims; or in the alternative, applicant respectfully requests further clarification to support a proper prima facie case.

#### **Rejections under 35 U.S.C. §103(a)**

Claims 30 and 37 are rejected under 35 U.S.C. §103(a) as being unpatentable over Huebsch et al. (5,853,422) in view of Shaw as noted above and in further view of Goldstein et al. (U.S. Patent No. 6,143,037).

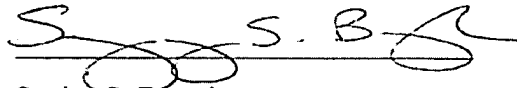
As noted above, applicant disagrees that the Office Action presents a proper prima facie case of obviousness. The addition of Goldstein et al. does nothing to remedy this deficiency. As a result, applicant contends all pending claims are allowable and respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No. 50-3973 referencing Attorney Docket No. TSNMNP00100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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